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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,328	08/21/2003	Rodolfo R. Llinas	05986/100K521-US1	7569

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EXAMINER

NATNITHITHADHA, NAVIN

ART UNIT	PAPER NUMBER
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3735

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/645,328

Applicant(s)

LLINAS, RODOLFO R.

Examiner

Navin Natnithithadha

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Claims 37-38 have been cancelled. Claims 1-36 are pending.

Response to Arguments

2. Applicant's arguments with respect to claims 10-17, 28, and 29 have been considered but are moot in view of the new ground(s) of rejection.

Drawings

3. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings are informal. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 10-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 states "an electrode that is smaller than 10 [micrometers]." However, Applicant's Specification, on page 10, line 2, specifically discloses "[t]he diameter of each electrode can be 0.5-10 [micrometers]." Thus, the scope of Applicant's claimed invention is limited to the diameter of the electrode is within the range of 0.5-10 micrometers. The claim language of "an electrode that is smaller than 10 [micrometers]" implies that the an electrode, e.g. wire or contact, in the length direction and the width direction must be smaller than 10 micrometers, which is not the scope of the Applicant's disclosure as shown in Figures 2 and 6B.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 10, 14, 18-21, and 26-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Howard, III, US 5,843,093 A ("Howard").

Claims 10 and 14: Howard teaches a device (see figs. 17 and 21b), comprising a catheter (electrode support shaft) 137; and a plurality of electrode (microelectrodes) 135a that have a diameter smaller than 10 micrometers ("each bipolar neuron-

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monitoring microelectrode 135A is constructed of a pair of closely juxtaposed electrical contacts 136. Each electrical contact comprises a fine wire having a diameter in the range of 5 to 200 micrometers" see col. 26, lines 12-19).

Claims 1-5, 18-21, and 26-31: Howard teaches a method of sensing the activity of neural tissue or stimulating neural tissue (the device has a dual purpose electrode assembly which is used for both neuron-monitoring and detecting electrical signals to/from the patient's brain, see col. 1, lines 15-16 and col. 7, lines 44-60), comprising placing a plurality electrode 135A into a specific regions of a patient's brain, the electrode diameter being smaller than 10 micrometers (see col. 26, lines 12-19); and monitoring/providing a signal on the electrode by way of a wire connected to the electrode, wherein the signal is indicative of/stimulates the electrical brain activity of the neural tissue (see col. 7, lines 40-60); wherein the electrode comprises a sensing end, the sensing end of the electrode being placed in the blood vessel proximate to the neural tissue (see fig. 2, 8, 10, or 11A).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 6-8, 17, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard, as applied to claims 1, 16, and 18 above, and further in view of Lieber et al, US 2002/0117659 A1 ("Lieber").

Claims 6-8, 17, and 22-24: Howard does not explicitly teach nano-electrode(s) having a nano wire and a micro-wire. However, Lieber teaches nano-sensors comprising nano-electrodes 36 (see fig. 1a and paragraph 133) connected to nanowire 38 and electrical connections 22 (see fig. 1a and see paragraph 135). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Howard's microelectrodes 135A in order to have electrodes that are of sufficient size to be placed near brain tissue.

7. Claims 9 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard in view of Lieber, as applied to claims 6 and 22 above, and further in view of Imram, US 5,391,147 A ("Imram").

Claims 9 and 25: Howard and Lieber do not teach a cup-like end to nano-electrodes. However, a cup-like end to an electrode is a well-known structure to electrodes. For example, Imram teaches a catheter comprising an electrode 221 having a cup shaped end (see fig. 19 and col. 8, lines 47-52). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Howard's electrode 135A to have a cup shaped end in order to accurately sense the activity of neural tissue.

8. Claims 11, 12, 15, 16, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard as applied to claims 1, 10, and 14 above, and further in view of Kovacs et al, US 5,883,603 A ("Kovacs") or John, US 4,913,160 A ("John").

Claims 11, 12, 15, 16, 32, and 33: Howard teaches a processor 410 but does not teach what the components of the processor are. However, Kovacs and John teach similar implantable devices containing electrodes that have amplifiers, digital converters, multiplexers, and microprocessors for coupling to an electrode in order to provide signal processing. It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Howard's processor 410 to be connected to amplifiers, digital converters, and multiplexers in order to provide adequate signal processing of the electrical signals obtained from the microelectrodes 135A.

9. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Howard, as applied to claim 12 above, and further in view of over Hoek, US 6,615,067 B2 ("Hoek").

Claim 13: Howard does not teach a Schmitt trigger. However, use of a Schmitt trigger for converting analog signals to digital signals is well known in the art. For example, Hoek teaches a Schmitt trigger 307 connected to a filter 306 (see col. 6, lines 24-29). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Howard's processor 410 to include a Schmitt trigger in order to have accurate digital processing of an electrode signal.

10. Claims 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard, as applied to claim 1 above, and further in view of Rise, US 6,374,140 B1 ("Rise").

Claims 32-36: Howard does not teach the claimed subject matter. However, the claimed subject matter relates well-known electrode signal processing techniques in the art. For example, Rise teaches a device, comprising: a sensor 20 with an electrode for measuring electrical activity of the brain, a signal processor 30 including a filter 200 for filtering the signal received from the electrode (see col. 5, lines 24-34). The signal processor 30 performs extraction and pattern recognition of the signal to determine a brain state, i.e. seizure or normal brain activity (see col. 30-48). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Howard's invention to provide processing of the signal from the microelectrodes in order identify brain activity and detect seizure.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6,128,527 A additionally teaches the subject matter of the Applicant's claims. The Examiner suggests reviewing this patents before responding to the present Office Action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Navin Natnithithadha
Patent Examiner – GAU 3735
06 July 2006